

## **REMARKS**

Claims 21, 23-28, 30-35 and 44 are currently pending and under examination. In the Instant Office Action claim 27 is indicated to be ALLOWED and claims 21, 23-26, 28, 30-35 and 44 are indicated to be REJECTED.

### **I. The Amendments**

#### **a. Amendment to the Specification**

In response to the requirement made at page 5 of the Instant Office Action, Applicants have herein amended the specification at page 12, line 27, to insert the following heading: “Brief Description of the Drawings ”.

#### **b. Amendment to the Claims**

Applicants have herein amended the claims, as summarized below:

- Claims 21, 23 - 26, 28, and 30-33 have been amended in order to delete the terms “tautomer” and “isomer”.
- Claims 28, and 30-34 have been amended in order to add the phrase “pharmaceutically acceptable” before the word “salt”.
- Claim 44 has been cancelled.

No new matter has been introduced by the foregoing amendment. The amendment to the claims is submitted without conceding the correctness of any position asserted in the Instant Office Action, and Applicants reserve the right to file one or more further patent applications with respect to any subject matter canceled thereby.

Claims 21, 23-26, 28, 30-35 and 44, as currently amended, are now presented for further consideration.

### **II. The Rejections Under 35 U.S.C. 112, second paragraph**

Claims 21, 23-26, 28, 30-35 and 44 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly

claim the subject matter which Applicants regard as the invention. More specifically, it is alleged at page 4 of the Instant Office Action that:

- i) with respect to claims 21, 23, 28, 30-34 and 44, the phrase “pharmaceutically acceptable” needs to be inserted before the word “salt” in order to “conform with standard U.S. practice”;
- ii) with respect to claim 21, the term “tautomer” is unclear; and
- iii) with respect to claim 21, the term “isomer” is unclear.

Applicants respectfully request withdrawal of the foregoing rejections Under 35 U.S.C. 112, second paragraph, in view of the amendment submitted herewith and the arguments presented below.

I. First, with regard to the allegation under i) above:

(a) As applies to claims 28 and 30-34, each drawn to a pharmaceutical composition, without conceding the correctness of the allegation in the Instant Office Action that “standard U.S. practice” requires conformity with any particular claim format, and solely in order to expedite examination of the instant application, Applicants have amended said claims by inserting the phrase “pharmaceutically acceptable” before the word “salt”, thus obviating the basis for the rejection.

(b) As applies to claims 21 and 23, Applicants respectfully submit that the Examiner may not have fully appreciated that these claims are drawn neither to pharmaceutical compositions nor to pharmaceutical uses, but rather simply to certain chemical compounds and (as amended herein) their salts and hydrates. More particularly, Applicants are unaware of a rule of U.S. patent practice that requires the salts of claimed compounds to be limited *per se* to those which are “pharmaceutically acceptable”, nor does the Instant Office Action provide a supporting rationale therefore. Applicants respectfully request that if such a requirement is reiterated in a subsequent Office Action, the requirement will include a more expansive explanation of the rejection, including citation to an appropriate federal statute, rule, or authoritative administrative interpretation thereof.

(c) As applies to claim 44, without conceding the correctness of the Examiner's allegation and solely in order to expedite examination of the instant application, Applicants have cancelled this claim, thus obviating the rejection thereof.

In sum with respect to the allegation under i) above, Applicants respectfully submit that the amendment of claims 28 and 30-34 and the cancellation of claim 44 has obviated the instant grounds for rejection of said claims. Further, Applicants respectfully submit that the instant grounds for rejection of claims 21 and 23 has been obviated by Applicants' argument above.

II. Second, with regard to the allegations under ii) and iii) above, without conceding the correctness of the allegation in the Instant Office Action that the terms "tautomer" and "isomer" are unclear, and solely in order to expedite examination of the instant application, Applicants have amended claims 21, 23-26, 28 and 31-33 in order to remove said terms therefrom.

In sum with respect to the allegations in the Instant Office Action under i), ii) and iii) above, Applicants respectfully submit that the amendment of the claims and the arguments presented herein have obviated the bases for rejection of the claims. Accordingly Applicants request reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. 112, second paragraph.

### **III. The Rejections Under 35 U.S.C. 112, first paragraph**

Claims 21, 23-26, 28, 30-35 and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. More specifically, it is alleged at page 5 of the Instant Office Action that

the claims contain new matter that was added to the claims which does not have clear support in the original specification, claims or drawings. Claim 21 includes the term "piperidino" in the last line of the definition of the R group.

Applicants respectfully traverse this rejection.

(a) First, as applies to claims 21, 23-26, 28, 30-35, Applicants direct the Examiner's attention to the paragraph bridging pages 2-3 of the specification, which provides, in relevant part, that:

... the meaning of R<sub>1b</sub> is [...] saturated *N*-containing heterocyclic moiety, preferably a group containing pyrrolidino, *piperidino*, piperazino or morpholino ring;

(emphasis added). Applicants further direct the Examiner's attention to Example 39, found in Table I at page 34 of the specification, in which a piperidino-carboxy moiety is provided at the R position. Since the definition of R includes, *inter alia*, R<sub>1b</sub>-CO, Example 39 represents a situation wherein R<sub>1b</sub> is a piperidino moiety.

(b) Second, as applies to claim 44, without conceding the correctness of the Examiner's allegation and solely in order to expedite examination of the instant application, Applicants have cancelled this claim, thus obviating the rejection thereof.

As demonstrated in foregoing paragraphs (a) and (b), with respect to claims 21, 23-26, 28, and 30-35, there is ample support in the specification for including "piperidino" within the definition of the R group. Further with respect to claim 44, this claim has been cancelled, thus obviating the rejection with respect thereto. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 21, 23-26, 28, 30-35 and 44 under 35 U.S.C. 112, first paragraph.

#### **IV. The Rejection Under 35 U.S.C. 102(e)**

Claim 44 has been rejected under 35 U.S.C. 102(e) as being unpatentable over Aranyi et al., WO 03/074500 ("Aranyi"). Applicants respectfully traverse this rejection.

Without conceding the correctness of the Examiner's allegation and solely in order to expedite examination of the instant application, Applicants have cancelled claim 44, thus obviating the rejection thereof. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 44 under 35 U.S.C. 102(e)

**IV. Conclusion**

In view of the forgoing amendment and remarks, Applicants respectfully submit that the present application in condition for allowance. Early notice to this effect is requested.

If there are any issues that can be resolved by a telephone conference or an Examiner's amendment, the Examiner is invited to call the undersigned attorney at (908) 231-5705.

Respectfully submitted,

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/ Brian R. Morrill /

Brian R. Morrill  
Registration No. 42,908  
Attorney for Applicants

sanofi-aventis U.S.  
U.S. Patent Operations  
1041 Route 202-206  
MAIL STOP: BWD-303A  
Bridgewater, NJ 08807-0800  
Telephone: 908-231-5705  
Telefax: 908-231-2626

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